

### REMARKS

Claims 9 and 12 have been amended to overcome the informalities identified by the Examiner.

The rejection of claims 11 and 15 – 16 under 35 USC 112, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is respectfully traversed. Claim 11 has been amended as suggested by the Examiner and claims 15 and 16 have been cancelled. Accordingly, the rejection of claims 11 and 15 – 16 under 35 USC 112 should now be withdrawn.

The rejection of claims 1 – 6, 8 – 10 and 17 under 35 USC 103(a) as being unpatentable over Komiya is respectfully traversed.

The present invention is directed to a cyclosporin preparation which is readily miscible with water and forms a stable cyclosporin solution. The invention provides colloidal solutions which are stable in water and which can be diluted with water as desired without precipitation of cyclosporine. This is achieved by the combination of four essential components: cyclosporin, dextran, an anionic surfactant and a non-ionic surfactant.

Dextran in the claimed cyclosporin solution is not employed as a pharmaceutically active component but, as the anionic and the non-ionic adjuvant to obtain the goals set out above.

Komiya, U.S. Patent No. 5,504,068, discloses a topical preparation containing only cyclosporin as an active ingredient, an organic solvent, not necessarily a solvent miscible with water, a fatty acid ester, an oily substance and a surfactant. Any surfactant is good for the purpose of the topical preparation disclosed by Komiya. Komiya does not teach or suggest the need to include, like in the present invention, an anionic surfactant plus a non-ionic surfactant.

Thompson, U.S. Patent No. 5,425,954, discloses a composition for topical application to the skin comprising a mixture of panthenol, cod liver oil, alpha tocopherol acetate, arginine, isoleucine, leucine, methionine, phenylalanine, threonine and valine in admixture with a suitable carrier. Panthenol is used as one of several pharmaceutically active ingredients. Although emulsifiers and detergents are mentioned by Thompson as optional ingredients there is no teaching of surfactants that have to be included as compulsory ingredients. Moreover, there is no teaching that an anionic plus a non-ionic surfactant must necessarily be included.

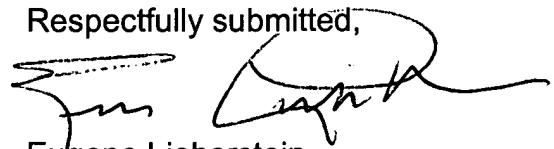
The cited prior art does not teach a cyclosporin solution which is readily miscible with water and forms a stable cyclosporin solution therein. No guidance is provided by Komiya, even when taken together with Thompson, to include dexpanthen as an adjuvant for anionic surfactant as well as a non-ionic surfactant as taught and claimed in the subject application.

For all of the above reasons claims 1 – 6, 8 – 10 and 17 are believed patentable over the teaching of Komiya '068 and the rejection thereof should be withdrawn.

Applicant acknowledges that claims 7 and 12 – 14 have been indicated to contain allowable subject matter.

Reconsideration and allowance of claims 1 – 14 and 17 is respectfully solicited.

Respectfully submitted,



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#### MAILING CERTIFICATE

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as first class mail in an envelope addressed: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on June 9, 2004.



Date: June 9, 2004



LISTING OF CLAIMS:

1. (previously presented) Cyclosporin solution comprising dextranthenol, an anionic surfactant and a nonionic surfactant.
2. (previously presented) Cyclosporin solution according to claim 1, in which the cyclosporin is cyclosporin A.
3. (previously presented) Cyclosporin solution according to claim 1 where the solution comprises 0.2-2 parts by weight of dextranthenol, 0.2-1 part by weight of anionic surfactant and 0.5-6 parts by weight of nonionic surfactant per part by weight of cyclosporin.
4. (previously presented) Cyclosporin solution according to claim 1 which additionally comprises a diluent.
5. (previously presented) Cyclosporin solution according to claim 4, in which the diluent content is 10-40% by weight based on the total weight of the solution.
6. (previously presented) Cyclosporin solution according to claim 4 in which diluent is ethanol.
7. (previously presented) Cyclosporin solution according to claim 1 in which the anionic surfactant is sodium lauryl sulfate.
8. (previously presented) Cyclosporin solution according to claim 1 in which the nonionic surfactants are polysorbate 80 and glycerol-polyethylene glycol oxystearate.
9. (currently amended) Cyclosporin solution according to claim 1 consisting of about 11% by weight of cyclosporin A, about 11% by weight of dextranthenol, about ~~5.6%~~ 5.6% by weight of anionic surfactant, about 55.6% by weight

of a mixture of nonionic surfactants and about 16.8% by weight of a diluent, in particular ethanol.

10. (previously presented) Cyclosporin solution according to claim 1 consisting of about 19-26% by weight of cyclosporin A, about 8-10% by weight of dextran, about 8-10% by weight of anionic surfactant, about 44-50% by weight of nonionic surfactant and about 12-14% by weight of a diluent.

11. (currently amended) A Oral pharmaceutical component comprising a an oral solution according to claim 1.

12. (currently amended) Pharmaceutical composition according to claim 11, where the solution is used to fill capsules.

13. (previously presented) Pharmaceutical according to claim 12, where the capsules are soft gelatin capsules.

14. (previously presented) Pharmaceutical according to claim 11, where the solution is in the form of an oral solution.

15. (cancelled)

16. (cancelled)

17. (previously presented) The cyclosporin solution of claim 1 wherein the nonionic surfactant is a mixture of nonionic surfactants.